JUN 15 2000

NDA 12-141/S-083
NDA 12-142/S-101

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: Joseph A. Linkewich, Pharm.D.
Director, U.S. Regulatory Liaison
Worldwide Regulatory Affairs

Dear Dr. Linkewich:

Please refer to your supplemental new drug applications received December 13,1996, submitted December 17,1996, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytoxan Tablets (cyclophosphamide tablets, USP) and Lyophilized Cytoxan (cyclophosphamide for injection, USP).

We also refer to your amendments of December 23, 1999, received December 29, 1999.

These supplemental new drug applications provide for the addition of the following subsection to the PRECAUTIONS section of the package insert:

> Pediatric Use
> The safety profile of CYTOXAN in pediatric patients is similar to that of the adult population (See ADVERSE REACTIONS section).

Please note that the draft labeling submitted with this supplemental application has been superseded by the supplemental new drug applications, Special Supplements-Changes Being Effected, NDA 12-141/S-084 and NDA 12-142/S-102, dated August 25, 1998, received August 28,1998 and approved May 28,1999, with the exception of the Pediatric Use subsection which has not been implemented.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended. Accordingly, these supplemental applications providing for the addition of the Pediatric Use subsection in the PRECAUTIONS section are approved effective on the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL